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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,162	01/16/2002	John H. Crowe	800189-0012 (6829-60508)	3071

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EXAMINER

CHEN, SHIN LIN

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 04/22/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/052,162

Applicant(s)

Crowe et al.

Examiner

Shin-Lin Chen

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-61 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Art Unit: 1633

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-7, drawn to a process for increasing cooperativity of a phase transition of an erythrocytic cell comprising providing an erythrocytic cell having an alcohol and removing at least a portion of the alcohol from the erythrocytic cell to increase cooperativity of the cooperative phase transition of the erythrocytic cell, classified in class 435, subclass 375.
 - II. Claims 8-15, drawn to a process for providing a phase transition temperature range in an erythrocytic cell comprising providing an erythrocytic cell having an alcohol and at least two phase transition temperature ranges and removing at least a portion of the alcohol from the erythrocytic cell to produce an erythrocytic cell having at least three phase transition temperature ranges, classified in class 435, subclass 375.
 - III. Claims 16-36 and 43-49, drawn to a process for loading an oligosaccharide into erythrocytic cells by removing at least a portion of the alcohol from the erythrocytic cell to produce an erythrocytic cell having at least three phase transition temperature ranges and disposing said cells in an oligosaccharide solution for loading an oligosaccharide into the erythrocytic cells, the loaded erythrocytic cells, and a process for preparing the loaded cells, classified in class 435, subclasses 101 and 325.

Art Unit: 1633

- IV. Claims 37-42, drawn to a process for increasing the survival of dehydrated erythrocytic cells after storage comprising removing alcohol from the erythrocytic cells, loading the erythrocytic cells with a preservative, and dehydrating the erythrocytic cells, storing the dehydrated cells, and rehydrating the stored dehydrated cells, classified in class 435, subclass 374.
- V. Claims 50-52, drawn to a solution for loading erythrocytic cells comprising reduced-alcohol erythrocytic cells having three transition temperature ranges, and an oligosaccharide solution containing the reduced-alcohol erythrocytic cells, classified in class 514, subclass 23.
- VI. Claims 53-61, drawn to a dehydrated composition comprising freeze-dried reduced-alcohol erythrocytic cells loaded with trehalose, and a process for preparing said dehydrated composition, classified in classes 424 and 435, subclasses 93.1 and 374, respectively.

2. The inventions are distinct, each from the other because of the following reasons:

Group I-IV and VI are distinct from each other because they are drawn to different scientific considerations: a process for increasing cooperativity of a phase transition of an erythrocytic cell, a process for providing phase transition temperature ranges in an erythrocytic cell, a process for loading an oligosaccharide into erythrocytic cells or preparing loaded erythrocytic cells, a process for increasing the survival of dehydrated erythrocytic cells after storage, and a process for preparing a dehydrated composition. They are different methods that

Art Unit: 1633

differ at least in objectives, method steps, reagents and doses used, schedules used, response variables, and criteria of success. They have different classifications and the search would not be coextensive. Thus, group I-IV and VI are patentably distinct from each other.

Groups III, V and VI are distinct from each other because they are drawn to different compositions having different chemical structure, physical properties and biological functions, and requiring separate search: loaded erythrocytic cells, a solution for loading erythrocytic cells comprising reduced-alcohol erythrocytic cells or an oligosaccharide solution containing alcohol-reduced erythrocytic cells, and a dehydrated composition. Further, a solution comprising reduced-alcohol erythrocytic cells can be used to produce various proteins of erythrocytic cells and such use is different from the use of loaded erythrocytic cells for blood transfusion. They have different classifications and require separate search. Thus, groups III, V and VI are patentably distinct from each other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Art Unit: 1633

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on (703) 305-4051. The fax phone number for this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.

A handwritten signature in black ink, appearing to read 'S. L. Chen', is positioned above the printed name.